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EXAMINER

PATTERSON, MARC A

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/811,277	Applicant(s) ZHONG ET AL.	
	Examiner Marc A. Patterson	Art Unit 1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-52 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 3-52 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. Claim 6 is objected to because of the following informalities: The phrase 'Parmax SRP' is a tradename and therefore renders the claim indefinite. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 3, 6 – 10, 14 – 16, 19 – 24, 27 – 37, 39 – 42 and 51 – 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Rau et al (U.S. Patent No. 6,024,722).

With regard to Claims 3 and 6, Rau et al disclose a medical device (catheter; column 3, line 59) comprising an elongate flexible element (shaft; column 3, line 60) made from a first polymer that is a rigid rod polymer (column 9, lines 63 – 65) that is thermoplastic (undergoing melt flow; column 10, line 12).

With regard to Claims 7 – 9, the medical device is an intravascular guidewire (column 4, lines 14 – 15), therefore a core wire, which is intravascular (used in angioplasty; column 2, line 22); the core wire therefore extends from a position proximate the proximal end of the guidewire to a position proximate the distal end of the guidewire..

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With regard to Claim 10, the core wire comprises a plurality of elongate longitudinally extending threads made from the polymer (parallel aligned filaments; column 9, line 5).

With regard to Claim 14, the flexible element is a sleeve extending over the wire (column 4, lines 12 – 15; Figure 1).

With regard to Claim 15, Rau et al disclose a second sleeve, disposed on the first, made from the polymer (outer layers; column 10, line 20).

With regard to Claim 16, the sleeve is an extruded tube (column 5, line 47).

With regard to Claims 19 – 24 and 27 – 28, the sleeve disclosed by Rau et al is a mesh and a weave (satin weave; column 9, line 3).

With regard to Claim 29, Rau et al disclose an inner sleeve and an outer sleeve, the flexible elongate member comprising a plurality of elongate threads disposed between the inner sleeve and the outer sleeve (the elongate member comprises a weave comprising yarn having polymeric material on its inner and outer surfaces; column 9, lines 10 – 15).

With regard to Claims 30 – 31, Rau et al disclose a blend of the first polymer and a second polymer (blend layer; column 9, line 59).

With regard to Claims 32 – 35, the medical device disclosed by Rau et al comprises a balloon (column 3, lines 60 – 66), therefore balloon sleeve.

With regard to Claims 36 – 37 and 39, the sleeves disclosed by Rau et al are extruded by any extruder (column 3, lines 55 – 57), therefore including coextrusion of the first polymer in a first layer and the second polymer in a second layer.

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With regard to Claims 40 and 51 – 52, Rau et al disclose that the medical device, comprising a crosslinkable polymer, is known in the art (thermoset polyimide; column 1, line 43); Rau et al therefore disclose a second polymer which is crosslinked or is not crosslinked.

With regard to Claims 41 – 42, the balloon disclosed by Rau et al has a thickness of 1 mil (0.001 inches; column 5, lines 48 – 50).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4 – 5, 11 – 13, 17, 25 – 26 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al (U.S. Patent No. 6,024,722).

Rau et al disclose a rigid rod polymer and core wire and a first layer and a sleeve as discussed above. With regard to Claims 4 – 5, Rau et al fail to disclose a polymer comprising benzoyl substituted 1,4 phenylene units. However, Rau et al disclose a polymer comprising phenylene units (column 9, line 66). It would therefore have been obvious for one of ordinary skill in the art to have selected benzoyl substituted 1,4 phenylene units, as benzoyl substituted 1,4 phenylene units are among the known phenylene units.

With regard to Claims 11 – 13, 17 – 18, 25 – 26 and 38, Rau et al fail to disclose a core wire having a circular cross sectional shape and rectangular cross sectional shape

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and cruciate cross sectional shape and a sleeve which is a coil and a wound flat tape and a distal varying thickness to create a first region having a first compliance and a second region having a second compliance less than the first compliance. However, Rau et al disclose a wire, therefore having an elongate shape, and a sleeve and layer, therefore having a uniform thickness. It would have been an obvious matter of design choice to have provided a circular or rectangular or cruciate cross sectional shape of the core wire and sleeve having a coil shape and a flat tape shape and distal varying thickness of the layer of Rau et al, since such a modification would have involved a mere change in shape. A change in shape is generally recognized as being within the level of ordinary skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

6. Claims 45 – 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al (U.S. Patent No. 6,024,722) in view of Weissleder et al (U.S. Patent No. 5,514,379).

Rau et al disclose a medical device comprising a catheter as discussed above. With regard to Claims 45 – 50, Rau et al fail to disclose a catheter comprising a hydrogel coating and a therapeutic agent and a paramagnetic material comprising gadolinium III and a lubricious sheath disposed around the elongate member comprising a hydrogel polymer.

Weissleder et al teach a catheter comprising a lubricious coating (column 10, lines 35 – 40), therefore a sheath comprising a hydrogel comprising gadolinium III (column 4, lines 1 – 8) for the purpose of using a coating that is biocompatible and biodegradable (column 1, lines 10 – 14). One of ordinary skill in the art would therefore have

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recognized the advantage of providing for the coating of Weissleder et al in Rau et al, which comprises a catheter, depending on the desired biocompatibility and biodegradability of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a hydrogel coating and a therapeutic agent and a paramagnetic material comprising gadolinium III and a lubricious sheath disposed around the elongate member comprising a hydrogel polymer in Rau et al in order to obtain a coating that is biocompatible and biodegradable as taught by Weissleder et al.

7. Claims 43 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al (U.S. Patent No. 6,024,722) in view of Lau et al (U.S. Patent No. 6,517,570 B1).

Rau et al disclose a medical device comprising a rigid rod polymer as discussed above. With regard to Claims 43 – 44, Rau et al fail to disclose a device comprising a self – expanding stent comprising a plurality of struts.

Lau et al teach a rigid rod polymer (column 13, line 5) in the making of a self – expanding stent comprising a plurality of struts for the purpose of obtaining a stent that does not shorten upon delivery (column 2, lines 13 – 30). One of ordinary skill in the art would therefore have recognized the advantage of providing for the device of Lau et al in Rau et al, which comprises a rigid rod polymer, depending on the desired shortening of the end product.

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It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a device comprising a self-expanding stent comprising a plurality of struts in Rau et al in order to obtain a stent that does not shorten upon delivery as taught by Lau et al.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc A Patterson whose telephone number is 571-272-1497. The examiner can normally be reached on Mon - Fri 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marc A. Patterson 6/26/06
Marc A. Patterson, PhD.
Primary Examiner
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